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08/945,249	02/02/1998	RICHARD ANTHONY VERE HODGE	P31158	2467

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NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 430/2  
EAST HANOVER, NJ 07936-1080

EXAMINER

TRAVERS, RUSSELL S

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/14/2004

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Paper No. 20040706

Application Number: 08/945,249  
Filing Date: February 02, 1998  
Appellant(s): VERE HODGE ET AL.

*date mailed out  
7-14-04*

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Thomas R. Savitsky  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed April 23, 2004.

**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

**(6) *Issues***

The appellant's statement of the issues in the brief is correct.

**(7) Grouping of Claims**

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because factual statements with regard to the separation of claims 1 and claims 4 and 16-20 are not presented. To stand, or fall separately, the claims must be separately patentable over the art of record. The instant claims are not separately argued, or illustrated as separately distinguishable over the art of record.

**(8) Claims Appealed**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) Prior Art of Record**

<b>WO 92/00742</b>	<b>Kenig et al</b>	<b>Issued 23 January 1992</b>
<b>EP 0 388 049</b>	<b>Boyd et al</b>	<b>Issued 19 September 1990</b>

**(10) Grounds of Rejection**

Claims 1, 4 and 16-20 are rejected under 35 U.S.C. § 103 as being unpatentable over Kenig et al or Boyd et al, all of record.

Kenig et al or Boyd et al, all of record, teach the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicament are taught as useful for treating those viral diseases herein claimed. Claims 1, 4 and 16-20, and the primary references, as to:

1) various isomers employed as the preferred therapeutic agents.

The skilled artisan, possessing a compound for a particular therapeutic use possesses all isomers, analogs, homologs, bioisosteres, acids, esters and salts of such compounds for that same use. In the instant case, the claims read on employing

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compounds residing in the prior art, for the same use. Absent information illustrating some unexpected benefit residing in those prior art compounds, unidentified in the prior art; the instant claims, reading on obvious subject matter remain properly rejected as obvious.

**(11) Response to Argument**

Those arguments presented by Appellants are unconvincing. Both Kenig et al and Boyd et al disclose those phosphate esters herein envisioned. Although disclosure of either the instant esters, or isomers, is required for obviation in the instant case; these compounds are disclosed for the uses herein envisioned by Kenig et al (see page 3, paragraph 1) and Boyd et al (see page 2, line 20). . Examiner agrees the specific isomer is not disclosed, yet this disclosure is not required in the instant situation. Optical activity of organic compounds was first described in 1815 by Jean-Baptiste Biot; with the present knowledge of optical isomers firmly established by Louis Pasteur in the years after 1848. Identification of chiral centers residing in organic compounds is a skill taught in introductory organic chemistry courses, and well known to those of normal skill in the art. These facts are set forth by the Court in *In re ADAMSON AND DUFFIN*, 125 USPQ 233 (CCPA 1960), at page 234 (paragraph 2) where the court stated this information was set forth in a basic chemistry text, thus, constructively known by those of normal skill in the art. Possessing this information, the skilled artisan would possess all that information required to view the instant claims are obvious over the prior art of record. Examiner notes the cited prior art teaches the

instant compounds, in a racemic mixture, as useful for treating the HIV and Hepatitis etiological agents.

Examiner sees the *In re Steminski* 170 USPQ 343 (CCPA 1971) as not germane to the instant rejection. The Steminski Court was concerned with structural obviousness, not the separation of optical isomers as in the instant case (see page 347, [1]).

Appellants cite *In re Gurley*, 31 USPQ2d 1130 (CAFC 1994) incorrectly: with the proper citation set forth herein. To teach away, a prior art citation must provide a positive statement directing the skilled artisan away from the claimed invention. *In re Gurley, supra* fails to support that argument presented by Appellants: the prior art teaches away from the instant invention. Attention is directed to *In re Gurley, supra*, at 1132 (paragraph 2) stating a “known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.”. Thus, the disclosure of Earnshaw et al fails to rise to the level of a “teaching away”. Earnshaw et al based rebuttal argument is also fatally defective for another reason. Examiner notes the instant claims are directed to antiviral therapy, with the disclosure of Earnshaw et al directed to enzyme inhibition. Arguments directed to unclaimed limitations are moot; yet more importantly, Earnshaw et al state they have little understanding as to the nexus between these enzyme inhibitions and antiviral activity (see Earnshaw et al, page 2756, paragraphs 2-3). These citations simply fail to teach away from employing one isomer of an old and well known antiviral racemic mixture for this old and well known therapeutic use.

Appellants cite *The Gillette Co. v S.C. Johnson & Sons Inc*, 16 USPQ2d 1923 (CAFC, 1990), incorrectly, with the proper citation set forth herein. Examiner notes the court in *The Gillette Co. v S.C. Johnson & Sons Inc*, *supra* was concerned with the application of a “clearly suggested” standard for establishing obviousness, not the standard for a teaching away (see pages 1926-1927). Although the court did mention a teaching away, this reference is simply dicta, and not germane to the instant application (see page 1927, last paragraph).

The argument at the bottom of page 3 (in the instant Appeal Brief) constructively states Appellants have set forth data illustrating unexpected benefits residing in the isomer herein claimed at specification page 4, such arguments are not factually based. Page 4 of the specification fails to set forth any data illustration unexpected benefits residing in the claimed isomer, when compared to the racemic mixture, as required to overcome the instant obviousness rejection. Examiner notes the absence of any data supporting, or suggesting the unexpected superiority of the claimed isomers. Additionally, and most important, the averred data is not presented in declaration form as required for information to overcome the instant obviousness rejection. The proper vehicle for overcoming an obviousness rejection is data set forth in a declaration under 37 CFR 1.132 providing an illustration of unexpected benefits residing in the claimed subject matter when compared to the closest prior art. Appellants suggest, at page 4 of the specification, the instant (claimed) compounds “may be prepared in the manner as hereinafter described”, and possess activity against HIV and Hepatitis virus (see specification page 4). Simply stated, the instant specification fails to provide any

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showing of unexpected benefit sufficient to overcome the instant obviousness rejection.

Absent such evidence, set forth in declaration form, the instant arguments are not factually based, and thus, unconvincing.

As stated above for the rebuttal arguments based on Earnshaw et al; the disclosure of Vere Hodge et al fails to rise to the level of a "teaching away", or a showing of unexpected benefits. A Vere Hodge et al based rebuttal argument is also fatally defective for another reason. Examiner notes the instant claims are directed to antiviral therapy against HIV and the hepatitis etiological agents, with the disclosure of Vere Hodge et al directed to enzyme inhibition in Herpes virus. Arguments directed to unclaimed limitations are moot; yet more importantly Vere Hodge et al results, illustrated against the unrelated herpes virus, would be seen as not providing a nexus between these herpetic enzyme inhibitions and the herein claimed antiviral activity against HIV and Hepatitis. Examiner notes the Vere Hodge et al reference would have placed the skilled artisan in possession of that knowledge regarding the optical isomers residing in penciclovir, and the separation of these compounds, some two years prior to the instant application.

The "obvious to try" rebuttal argument based on *In re Geiger*, 2 USPQ2d 1276, (CAFC, 1987) are unconvincing. As noted above, Appellants are claiming methods for using penciclovir compositions to treat viral diseases. As stated above, the Examiner cited prior art teaches penciclovir as a racemic mixture, placing the skilled artisan in possession of all isomers. Absent some difference in kind between the various isomers the skilled artisan would have seen each isomer as *prima facie* obvious (see *In re*



*Adamson and Duffin*, 125 USPQ 233 (CCPA 1960)). The skilled artisan would have expected optical isomers to be separable and isomers so separated to exhibit physiological effects at varying levels. Possessing a compound known to contain chiral centers, places all the resultant compounds in the skilled artisan's possession. It would follow therefore, the instant claims recite *prima facie* obvious subject matter and are properly rejected under 35 USC 103. It is noted that all references cited by Examiner teach the claimed penciclovir as effective against viral diseases, as claimed herein. Thus, use of one or another optical isomer by the skilled artisan would have been seen as *prima facie* obvious, absent some difference in kind between the various isomers (see *In re Adamson and Duffin*, 125 USPQ 233 (CCPA 1960)). The Boyd et al and Kenig et al cited prior art teach anti-HIV and anti-hepatitis therapeutic activity residing in the parent compounds racemate. *In re Adamson and Duffin*, supra provide the motivation to employ the individual optical isomers for the same use. Nothing needs to be combined, as in Geiger, simply separated into obvious optical isomers using old and well known procedures, as herein recited.

As initially stated, both Kenig et al and Boyd et al disclose those phosphate esters herein envisioned. Although disclosure of either the instant esters, or isomers is required for obviation in the instant case, these are disclosed by Kenig et al (see page 3, paragraph[h] 1) and Boyd et al (see page 2, line 20) for the uses herein envisioned. Examiner agrees the specific isomer is not disclosed, yet this disclosure is not required in the instant situation. Identification of chiral centers residing in organic compounds is a skill taught in introductory organic chemistry courses, and well known to those of normal

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skill in the art. These facts are set forth by the Court in *In re ADAMSON AND DUFFIN*, 125 USPQ 233 (CCPA 1960), at page 234 (paragraph 2) where the court stated this information was set forth in a basic chemistry text, thus, constructively known by those of normal skill in the art. Possessing this information, the skilled artisan would possess all that information required to view the instant claims are obvious over the prior art of record. Examiner notes the instant cited prior art teach the instant compounds, in a racemic mixture, as useful for treating the HIV and Hepatitis etiological agents.

As stated above, the skilled artisan, possessing a compound for a particular therapeutic use possesses all optical isomers of such compounds for that same use. In the instant case, the claims read on employing compounds residing in the prior art, for the same use. Absent information illustrating some unexpected benefit residing in those prior art compounds, unidentified in the prior art; the instant claims, reading on obvious subject matter remain properly rejected as obvious.

Additionally, the skilled artisan would easily identify a chiral center in the claimed compound, and the skilled artisan possesses that information required for separation of such optical isomers. It is well settled patent law that the skilled artisan, knowing a compound contains an asymmetric carbon atom, possesses all resultant optical isomers. The skilled artisan in possession of a compound for a specific therapeutic use, possesses all isomeric forms of the compound for the old and well known antiviral utility. It is well known in the pharmaceutical art that various optical isomers will exhibit biological effects at various levels. Absent unexpected benefits residing in these old

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and well known compositions and methods for their use, the instant claims are properly rejected under 35 USC 103.

Applicants aver a showing of unexpected benefits residing in the specification at page 4; Examiner was unable to locate a showing of unexpected benefits. As stated previously; evidence as to unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). The data provided by Applicants is neither clear, nor convincing or reasonably commensurate in scope with the instant claims, and fails to state the nature, or magnitude, of the argued, yet undisclosed, unexpected benefits. Absent claims commensurate with a showing of unexpected benefits, or a showing reasonably commensurate with the instant claims, such claims remain properly rejected under 35 USC 103. Evidence supporting un-obviousness by virtue of possessing unexpected benefits must be submitted in declaration form. All information in the specification is attested, as should any information subsequently filed. If Applicants attest to published data, that such data was done at their direction and guidance; these averments will support averments of un-obviousness.

Examiner cited prior art teaches those phosphate esters herein envisioned. The Examiner cited prior art taught the instant compounds as possessing chiral atom, thus, producing optical isomers. Possessing a compound for a medicinal use, this skilled artisan possesses all isomers for this compound. Absent a illustration of unexpected benefits residing in one, or another, isomer these uses are obvious to the skilled artisan.

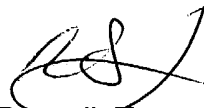
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The references herein relied upon establish a strong prima facie case of obviousness as to applicants' invention. The claimed subject matter is of such a nature that the differences between said subject matter and the teachings of the prior art of record would have rendered applicants' subject matter as a whole obvious to those skilled in the art at the time of applicants' invention. The references clearly establish that the claim designated components were old, of known character and that one skilled in the art would have been motivated to employ said components in the manner herein claimed to obtain the claimed, expected results. The claims are therefore properly rejected under 35 USC 103.

Thus, the instant claims must stand, or fall, together. For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,



Russell Travers, J.D., Ph.D.

Primary Examiner

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July 7, 2004

**SHENGJUN WANG**  
**PRIMARY EXAMINER**



Conferees



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